

APPENDIX B. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K904302

MAY -9 1997

Applicant Information:

Date Prepared:	October 28, 1996
Name:	Heartport, Inc.
Address:	200 Chesapeake Drive Redwood City, CA 94063
Contact Person:	Marianne C. Drennan
Phone Number:	(415) 306-7900
Fax Number:	(415) 306-7905

Device Information:

Classification	Class II
Trade Name:	Heartport™ Thoracic Trocar
Classification Name:	Cardiovascular Devices - Trocar 21 CFR 870.1390

Equivalent Devices:

The Heartport Thoracic Trocar is substantially equivalent in intended use and/or method of operation to the Origin Medsystems (a Guidant Corp.) - Surgical Trocar Thoracic.

Intended Use:

The Heartport Thoracic Trocars are intended to provide access to the thoracic cavity by inserting them into incisions in the intercostal spaces, with minimal-to-no rib retraction. The Heartport Thoracic Trocar allows endoscopic instruments, thoroscopes and accessory devices to be inserted and used during cardiothoracic surgery procedures.

510(k) Summary of Safety and Effectiveness (continued)**Comparison To Predicate Devices:**

The Heartport Thoracic Trocars are equivalent in intended use and operational characteristics to the Origin Medsystems (a Guidant Corp.) - Surgical Trocar Thoracic.

Non-Clinical Test Results:*Performance*

The Heartport Thoracic Trocar was evaluated *in vivo* for performance including insertion force, removal force and compatibility with endoscopic instruments and vision equipment. Performance testing demonstrated that the Heartport Thoracic Trocar is safe and effective, while meeting the anticipated clinical requirements for its intended use.

Biocompatibility

The materials used to fabricate the Heartport Thoracic Trocar are similar to those used in the predicate device. The materials used in the Heartport Thoracic Trocar have proven biocompatibility.

Summary:

Based on the intended use, product information, performance and biocompatibility data provided in this Notification, Heartport Thoracic Trocars have been shown to be substantially equivalent to a currently marketed predicate device.